Remarks

The Office Action mailed December 12, 2002 has been received and reviewed. Claims 1-7 and 10-22 are pending in the application. Claims 1-4 have been withdrawn from consideration, and are canceled herein. All non-withdrawn claims are rejected. The application is to be amended as otherwise set forth. All amendments are made without prejudice or disclaimer. New claims are to be added. It is respectfully submitted that no new matter has been added. Reconsideration is respectfully requested.

A. The Restriction Requirement:

The earlier restriction requirement has been withdrawn. (Paper No. 7, p. 2). In its place, a new restriction has been entered between the claims of Group I (including withdrawn claims 1-4) and Group II (including claims 5-7 and 10-22). Claims 5-7 and 10-22 were considered in the instant Office Action, although a rejoinder of claims is possible at a later date if the product is eventually found patentable.

B. Drawings:

The Office objected to FIGs. 3 and 4. They will be corrected before payment of the issue fee.

C. Claim Objections:

Claim 13 was objected to for use of the abbreviation "PRRSV". Claim 13 has been amended. Basis for the amendment is inherent throughout the application, but specific basis can be found at, for example, page 3, paragraphs 5 and 7, of the application as filed.

Claim 10 was objected to for depending from a non-elected base claim. Claim 10 has been amended to incorporate one portion of claim 1 from which it depended. Basis for the amendment is inherent throughout the application, but specific basis can be found in originally filed claim 1. New claim 27 is to be added to claim the "derivative" nucleic acid material in a different aspect. Basis for this amendment is inherent throughout the application, but specific basis can be found at, for example, page 8, paragraph 22 and page 26, lines 8-10, of the application as filed.

D. 35 U.S.C. § 112:

Claims 5-7 and 11-22 were rejected under 35 U.S.C. § 112, 2nd paragraph, as assertedly being indefinite. Reconsideration and withdrawal of the rejections in view of the amended claims is respectfully requested.

Specifically, the term "modified RNA virus" was thought indefinite as it could refer to a genetic modification or to a modification to the environment (*e.g.*, by purification). (Paper No. 7, page 4). Applicants have amended the rejected claims to state that the modification is a genetic modification. Basis for the amendment is inherent throughout the application, but specific basis can be found at, for example, page 21, paragraph 48, of the application as filed. Potentially, language along the lines of an "RNA virus modified by the means of recombinant DNA technology" might be considered if that were more acceptable to the Office. In view of the foregoing, applicants respectfully request that the rejection be withdrawn.

In claim 20, the terminology "derivative of either" was thought indefinite. The claim has been amended to remove the rejected terminology. In view of the foregoing, applicants respectfully request that the rejection be withdrawn.

E. 35 U.S.C. § 102:

Claims 5-7 were rejected under 35 U.S.C. § 102 as assertedly being anticipated by Frolov et al. or Moormann et al. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 5 has been amended to be directed to arterivirus. Claims 6 and 7 have been amended to be directed to RNA virus having a genome greater than 15kb. Neither Frolov et al. nor Moormann et al. discloses either of these features, and the anticipation rejections should be accordingly withdrawn in view of the amendments.

F. 35 U.S.C. § 103:

Claims 5-7 and claims 10-22 were rejected under 35 U.S.C. § 103 as assertedly

being anticipated by Wensvoort et al. and Moormann et al. Applicants respectfully traverse the rejections.

As a first point, there is no real motivation to combine the references as such motivation must be found in the references themselves, and such is not the case here.

Furthermore, there is no reasonable expectation of success. For instance, claims 6 and 7 and the claims dependent thereon are directed to RNA virus having a genome greater than 15kb. As described in the application, at the time of the invention, no one expected the described process to work on such large genomes.

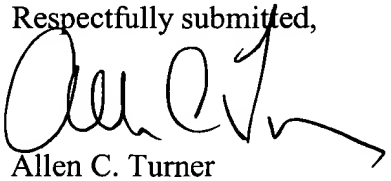
Also, with respect to claims such as claims 20, 11-19, 21, 22, and 25, neither reference discloses using "a host cell not susceptible to infection with the RNA virus" or the benefits derived therefrom. Accordingly, such claims cannot be made obvious over the cited references.

Applicants accordingly request that the rejection be withdrawn.

Conclusion

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: June 12, 2003

VERSION SHOWING CHANGES MADE

5. (Amended) [A modified]An RNA virus comprising a recombinant nucleic acid[, said recombinant nucleic acid comprising at least one full-length DNA copy or]selected from the group consisting of

an *in vitro*-transcribed RNA copy [or a derivative of either] of an arterivirus genome and

an *in vitro*-transcribed RNA copy of the arterivirus genome lacking the genetic information encoding arterivirus envelope protein.

6. (Amended) A vaccine [comprising a modified RNA virus, said modified RNA virus] comprising a recombinant nucleic acid [which comprises] comprising at least one full-length DNA copy or *in vitro*-transcribed RNA copy [or a derivative of either] of an RNA virus's genome, wherein the RNA virus's genome is greater than 15 kb.

7. (Amended) A cell culture [infected] with [a modified RNA virus, said modified RNA virus comprising] or transfected with a recombinant nucleic acid [which comprises] comprising at least one full-length DNA copy or in vitro transcribed RNA copy [or derivative of either] of an RNA virus's genome, wherein the RNA virus's genome is greater than 15 kb.

10. (Amended) A recombinant nucleic acid comprising an infectious clone based upon a positive strand RNA virus's genome, wherein the genome is at least about 15 kb, said infectious clone produced by [the method according to claim 1] a process comprising:

producing a recombinant nucleic acid comprising a nucleic acid sequence selected from the group consisting of an *in vitro*-transcribed RNA copy of the RNA virus's full length genome and DNA complementary to the RNA virus's full length genome.

11. (Twice amended) The [modified] RNA virus of claim 20 wherein the [infectious clone] RNA virus is based on the genome of a virus of the order Nidovirales.

12. (Twice amended) The [modified] RNA virus of claim 11 wherein the

infectious clone is based on a virus of the family Arteriviridae.

13. (Twice amended) The [modified] RNA virus of claim 12 wherein the virus is [PRRSV] porcine reproductive and respiratory syndrome virus.

14. (Twice amended) The [modified] RNA virus of claim 20 wherein the infectious clone further comprises at least one nucleic acid sequence encoding a virulence marker and/or a serological marker particular to said positive strand RNA virus, and wherein said at least one nucleic acid sequence has been modified to effect a change in virulence and/or a change serological immune response.

15. (Twice amended) The [modified] RNA virus of claim 14 wherein the nucleic acid sequence encoding said virulence or serological marker or virulence and serological markers is located within any of the genome's open reading frames encoding structural viral proteins.

16. (Twice amended) The [modified] RNA virus of claim 20 wherein said infectious clone further comprises a nucleic acid sequence comprising at least one open reading frame and wherein said at least one open reading frame is substituted by an ORF7.

17. (Twice amended) The [modified] RNA virus of claim 20 wherein at least one additional heterologous nucleic acid sequence is inserted into the infectious clone, allowing the infectious clone to serve as a delivery system for an additional heterologous nucleic acid sequence.

18. (Twice amended) The [modified] RNA virus of claim 17 wherein said heterologous nucleic sequence encodes an antigen.

19. (Twice amended) The [modified] RNA virus of claim 20 wherein said infectious clone further comprises a nucleic acid sequence comprising at least one open reading frame, said at least one open reading frame having been modified to effect a change in virulence and/or a change in serological response in vivo in a cell into which the infectious clone has been introduced.

20. (Twice amended) [A modified] An RNA virus [comprising an infectious clone] based upon [a positive strand] an RNA virus's genome, said RNA virus being of the type having a positive strand RNA and further having genetic information encoding at least one envelope protein, said [infectious clone] genetically modified RNA virus produced by a process comprising:

[generating] transfecting a host cell with a recombinant nucleic acid comprising [at least one full-length DNA copy or at least one in vitro-transcribed RNA copy or a derivative of either said at least one DNA copy or said at least one in-vitro transcribed RNA copy and] a nucleic acid sequence selected from the group consisting of an *in vitro*-transcribed RNA copy of the RNA virus's full length genome, an *in vitro*-transcribed RNA copy of the RNA virus genome but lacking the genetic information needed to produce enveloped, infectious RNA virus, DNA complementary to the RNA virus's full length genome, and DNA complementary to the RNA virus genome, but lacking genetic information needed to produce enveloped, infectious RNA virus; wherein the [RNA virus's genome is at least about 15 kb] host cell is not susceptible to infection with said RNA virus, to produce said genetically modified RNA virus.

22. (Amended) A vaccine comprising the [modified] RNA virus of claim 20.

22. (Amended) A cell culture infected with the [modified] RNA virus of claim 20.